

App. No. 10/521,234  
Office Action Dated November 30, 2009

## REMARKS

Favorable reconsideration is respectfully requested in view of the above amendments and following remarks. Claim 15 has been amended. The amendment to claim 15 is supported by the original disclosure, for example at page 2, lines 17-18 of the specification. No new matter has been added. Claims 11, 14 and 15 are pending.

into account.

### *Claim rejections - 35 U.S.C. § 103*

Claims 11, 14 and 15 are rejected under 35 USC 103(a) as being unpatentable over Komori et al. (EP 1002874) and Glossary of class names of organic compounds (PAC, 1995, 67, 1307, pages 1351-1396), in view of Bauman et al. (US Patent No. 4,265,810) and Ledis et al. (US Patent No. 5,731,206) and further in view of Kaminagayoshi et al. (EP 0158964) and Ishimaru et al. (US Patent No. 6,127,138). Applicants respectfully traverse the rejection.

Komori indicates at page 5, paragraphs [0043-0044] that in their method, hemolysis can involve the use of a surfactant, and where a surfactant is used, they are added in certain concentrations with respect to the blood cells. Komori further indicates at page 2, paragraphs [0005] and [0010] and page 6, paragraph [0045] that the hemolyzed blood sample is then pretreated with a tetrazolium compound so as to eliminate the influence of the reducing substance. Thus, it is clear that Komori teaches using the surfactant for hemolyzing blood cells and the tetrazolium compound for inhibiting the activities of the reducing substance. On the other hand, claim 15 recites treating a sample containing the glycated protein with a protease in the presence of a sulfonic acid compound and a nitro compound in order to degrade glycated protein quickly. Nothing in Komori provides any reason to expect that the surfactant and the nitro compound as recited in claim 15 could be added together with a protease to degrade the analyte quickly.

Bauman, Ledia, Ishimaru and Kaminagayoshi do not remedy the deficiencies of Komori. Bauman indicates using the 4-aminoazo-benzene-4'-sodium sulfonate (AABSS) to synthesize a dye by treating the AABSS with sodium nitrite and sulfamic acid to diazotize the AABSS (col. 4, line 65 to col. 5, line 9). Ledis indicates using activated phenols with an electron withdrawing group, for example, 2,4-dinitrophenol, for rapidly partitioning whole blood sample into an essentially intact leukocyte fraction and a lysed erythrocyte fraction (col. 5, lines 11-13 and col.

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6, lines 45-63). Ishimaru and Kaminagayoshi are silent as to the sulfonic acid compounds and the nitro compounds of claim 15. Thus, even when combined, the references fail to provide any reason to expect that by replacing the surfactant of Komori, which is used for hemolysis, with the AABSS of Bauman, which is used as a precursor for a dye, and by replacing the nitro compound of Komori, which is used for inhibiting the activities of reducing compounds, with the phenol of Ledis, which is used for partitioning a whole blood sample, the glycated protein can be degraded quickly in the presence of a protease as recited in claim 15.

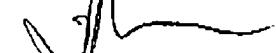
The rejection contends that one would have realized that a reducing agent is a substance that reduces another substance by supplying electrons to it, that compounds with electron withdrawing groups (in this case 2,4-dintrophenol) are oxidizing substances which are able to remove electrons from reducing agents, and that substituting one oxidizing agent with another would have given predictable results. However, Komori indicates that the presence of the tetrazole ring as being responsible for the desired effects, and therefore, one of ordinary skill in the art would clearly understand that their effect is derived from the tetrazolium structure, and would not focus on the nitro group alone. Thus, contrary to the rejection's position, one of ordinary skill in the art would not expect that a compound lacking the tetrazolium structure as described by Ledis, would have the same function as any of the tetrazolium compounds, especially those lacking the nitro group (see page 13-17 of Komori), as described by Komori. Accordingly, claim 15 and its dependent claims are patentable over the references, taken alone or together.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully submitted,

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